

REMARKS

Claims 44-70 are pending. Claims 51-59 and 70 are under examination and have been rejected. With this paper, claims 51, 52 and 70 have been amended. Applicants respectfully request reconsideration and withdrawal of the rejections for at least the following reasons.

Specification

Applicants note it is asserted in the Office Action that a new title is required. Applicants respectfully disagree and believe no replacement title is required, and note that there is no specific objection or rejection in regards to the title in the Office Action.

Rejections under 35 USC § 112

All the pending, non-withdrawn claims stand rejected based on the contention that they are indefinite via inclusion of the phrase “substantially free.” Applicants respectfully disagree that one skilled in the art would not be reasonably apprised of the meaning of this phrase, but have nevertheless amended claim 51 to delete reference to the term “substantially.” Basis for this amendment can be found in the specification as filed, for example, on page 10, lines 31-35.

Claim 52 has been amended to refer to comparison with a composition comprising *Neisseria* outer membrane vesicles that bind to human CEACAM1. Basis for this amendment can be found in the specification as filed at, for example, page 11, lines 1-8.

In view of the foregoing remarks and amendments referred to therein, Applicants believe the claim amendments introduce no new matter and obviate the stated rejections under 35 USC § 112. The Examiner is respectfully requested to reconsider and withdraw the rejections.

Rejections under 35 USC § 102(b)

Claims 51-56 and 70 stand rejected based on the assertion that they are anticipated by Zollinger et al. (U.S. Patent No. 6,558,677).

In response, Applicants point out that the instant claims have been amended to clarify that the method of the invention comprises administering a composition comprising *Neisseria*

outer membrane vesicles (“OMV”), wherein the OMV are free of *Neisseria* Opa that binds to human CEACAM1. Thus, the claims now recite a specific Opa protein and a specific CEACAM1. Since there is no disclosure or suggestion in Zollinger et al. of any *Neisseria* OMV that are free of *Neisseria* Opa that binds human CEACAM1, and since, as the Examiner has pointed out, the OMVs described in Zollinger et al. are free of Opa that binds to the murine CEACAM1 protein, the instant claims are not anticipated by the disclosure of Zollinger et al. The Examiner is accordingly requested to reconsider and remove the stated rejection.

Rejections under 35 USC § 103(a)

Claims 51-59 and 70 stand rejected based on the assertion that they are obvious over Zollinger et al. in view of Foster et al. (U.S. Patent No. 7,384,645).

In response, Applicants reiterate that there is no disclosure or suggestion in Zollinger et al. of any *Neisseria* OMV that are free of *Neisseria* Opa that binds human CEACAM1. Applicants further point out that there is also no such disclosure in Foster et al. Therefore, the combination of Zollinger et al. and Foster et al. is inadequate to render the present claims obvious. Moreover, Applicants emphasize that, prior to the present Application, there was no appreciation in the art of the technical problems associated with Opa proteins in *Neisseria* OMV-based vaccines (i.e., see passage spanning pages 7-8 of the application as filed). Accordingly, one skilled in the art would not be motivated to prepare *Neisseria* OMV that are free of *Neisseria* Opa that binds human CEACAM1 from the combination of Zollinger et al. and Foster et al. In this regard, the instant application discloses the unexpected discovery that *Neisseria* Opa protein suppresses immune responses via interaction with the human CEACAM1 receptor. Thus, the instant invention relates to removal of *Neisseria* Opa that binds human CEACAM1 from *Neisseria* OMV-based vaccines to provide improved vaccine formulations for meningococcal disease. In connection with this, the Examiner’s attention is respectfully directed to page 11, lines 1-14, and the passage spanning page 11, line 29 through page 12, line 3.

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Conclusion

In view of the foregoing amendments and remarks, Applicants believe all of the pending, non-withdrawn claims are now in condition for allowance and respectfully request the Examiner to reconsider the rejections and allow all of the claims.

It is believed no fee is due with this communication. If any fee is due or extensions of time are necessary during the prosecution of this application, such extensions are hereby requested and the fees due may be charged to Deposit Account No. 08-2442.

Respectfully submitted,

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